

Remarks/Arguments:

The invention relates to pharmaceutical compositions containing cyclosporine as the active ingredient. More specifically, the invention relates to orally administered pharmaceutical compositions comprising cyclosporine, ethanol, polyoxyethylene glycerol trioleate, and an oil component. The invention also relates to a method of preparing an orally administered pharmaceutical composition comprising the steps of: (1) dissolving cyclosporine in ethanol to form a solution; (2) combining polyoxyethylene glycerol trioleate and an oil component with the solution to form a mixture; and (3) diluting the mixture with an aqueous media to allow formation of a spontaneous emulsion.

Claims 1-30 are pending in this application. The Office Action rejects claims 1-30 under 35 U.S.C. § 103(a) as being unpatentable over Cho *et al.* (U.S. Patent No. 5,962,019) in view of Li *et al.* (*S.T.P. Pharma Sciences*, Vol. 10 (4), 2000) and Kovacs *et al.* (U.S. Patent No. 5,583,105). For a reference to qualify as prior art under § 103, it must also meet the requirements under § 102. For example, the reference must have a publication date more than one year prior to the filing date of the application to qualify as prior art under 35 U.S.C. § 102(b), and the reference must not describe the applicant's own work to qualify as prior art under 35 U.S.C. § 102(a). Because the Li *et al.* reference was publicly available less than one year before applicants' filing date and the Li *et al.* reference describes applicants' own work, the Li *et al.* reference is not prior art under 35 U.S.C. § 103.

According to M.P.E.P. § 2128.03, a journal article or other publication becomes available as prior art on the date it is received by a member of the general public. A publication disseminated by mail is not prior art until it is received by at least one member of the public. Thus, a magazine or technical journal is effective as of its date of publication (date when first person receives it) not the date it was mailed or sent to the publisher. *In re Schlittler*, 234 F.2d 882, 110 USPQ 304 (CCPA 1956).

The Li *et al.* reference is a publication appearing in *S.T.P. Pharma Sciences*, Vol. 10 (4), 2000. *S.T.P. Pharma Sciences*, which is published six times a year. The Li *et al.* reference was published in the 4th issue of the year 2000. To the best of our knowledge, after discussions with the inventors and the publisher, the first date that the 4th issue of Vol. 10 of *S.T.P. Pharma Sciences* was made available to the public was **September 8, 2000**, as

evidenced by a copy of the front page of the *STP Pharma Science* journal, on which is placed the date receipt stamp from the National Library of Medicine. A copy of the date-stamped front page is enclosed and the word "received" appears partially in the upper left hand portion of that document. Therefore, because the Li et al. reference was publicly made available less than one year prior to the applicants' filing date, the Li et al. reference is not prior art under 35 U.S.C. § 102(b).

The applicant's disclosure of his or her own work through a written article published within the year before the filing date of a patent application for the same subject matter, cannot be used against him or her under 35 U.S.C. § 102(a). *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (Katz stated in a declaration that the coauthors of the publication, Chiorazzi and Eshhar, "were students working under the direction and supervision of the inventor, Dr. David H. Katz". The court held that this declaration, in combination with the fact that the publication was a research paper, was enough to establish Katz as the sole inventor and that the work described in the publication was his own. In research papers, students involved only with assay and testing are normally listed as coauthors but are not considered co-inventors.)

As evidenced by the attached § 1.132 declaration, the *S.T.P. Pharma Sciences*, Vol. 10 (4), 2000, describes the work of the applicants. First, Dr. M. Groves is listed as a co-author of the article. In fact, as Dr. Groves' declaration states, the other listed co-author, Y. Li, was a student working at the University of Illinois of Chicago working under the direction and supervision of Dr. M. Groves. Moreover, the subject matter of the publication was derived from applicants, as Dr. Groves' declaration specifies. Accordingly, for the reasons set forth above, the Li et al. reference describes the applicants' own work. Therefore, it is not a proper reference under 35 U.S.C. § 102(a).

Because, the Li et al. reference was relied upon to reject claims 1-30 and because it is shown by this filing not to be prior art, the applicants submit that the rejection has been overcome.

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MGP-104US

For all of the foregoing reasons, the applicants respectfully request the Examiner's reconsideration of claims 1-30 of this application.

Respectfully submitted,



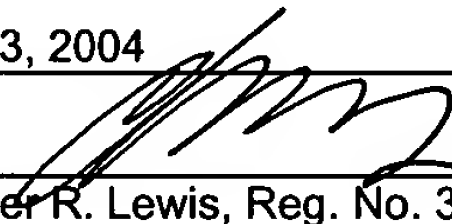
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